EXHIBIT M

PR800-011, Appendix I (v5)
Form Rev. CP2002GXJ001

Product Description Document

Project Name: Gynecare TVT Obturator
Version: 1 (initial release of document)

Approved by:	Name	Signature	Date
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Product Overview:

The product is a TVT Obturator system called "GYNECARE TVT *Obturator*" and is similar to TVT base device. It is used as a surgical method to treat SUI (stress urinary incontinence) in women. The device is a trans-obturator sub-urethral sling which uses an inside-out ("direct") approach, as opposed to the outside-in ("indirect") approach. The mesh placement relative to the urethra can be adjusted interoperatively prior to closing the vaginal incision.

Key components:

- Atraumatic winged guide to assist in locating the path for mesh placement following the initial dissection.
- Helical Passer which consists of two hollow plastic tubes attached to the extremes of the TVT mesh, pre-assembled onto two curved stainless-steel wire handles (one for each side: right and left)

The device is similar to the base TVT device in that it uses the same mesh, which is placed under the mid-urethra, and is used by the same surgical specialties and support personnel.

It differs from the base TVT device in that it is placed in a trans-obturator location (through the obturator foramen) rather than in a retro-pubic location.

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Product Functions and Features: (Including)

1) What is the real need for the new device?
This device is used to surgically treat SUI (stress urinary incontinence) in female patients. This device is intended for surgeons who choose to use a trans-obturator (inside-out) approach, to avoid the abdominal retropubic passage of the current TVT needles and reduces the associated risk of bladder, urethra, vessel and bowel puncture.

2) Where will the new device be used?
The system will be used in surgical procedures, similar to the current use of the TVT base device: in hospitals and one-day OR treatment centers.

3) Who will use the new device?
The same surgical specialties and support personnel will use this device as currently use TVT base device: Gynecologists, Urogynecologists, and Urologists. OR nurses & support staff will assist in the packaging and assembly of the device.

4) Are there any specific user factors which should be considered?
Same as TVT base device. Further, surgeons who have not previously performed a trans-obturator approach may require additional training.

5) How will the new device be used?
Same placement as the TVT base device, except it will be anchored through the obturator foramen

6) With what will the new device be used?
This system is a single-patient use kit which will contain all key components. Other standard OR surgical instruments will be required per TVT procedure (possibly without the need for cystoscopy).

7) How long will the new device be used?
It is a permanent mesh implant, surgically placed using disposable instruments.

8) What will the device be used to do?
This device is used to surgically correct SUI (stress urinary incontinence) in female patients (same indications as TVT).

9) If there are any competitive products existing, what distinguishing human factors have been determined?
This TVT *Obturator* device should reduce the risk of bladder, urethra, vessel and bowel perforation since it is placed from the inside-out (from under the urethra through the obturator foramen and out the upper thigh). The competition (AMS Monarc and PORGES UraTape/ObTape) is outside-in (from the upper thigh through the obturator and out under the urethra).

10) Are there any environmental issues to be considered? None

11) Are there any computer system components to be considered (chips; microprocessors; etc.)? None

12) Other questions related to the specific device to be developed. For Example: Human Factors, Sterility, Packaging, Safety, Transportation, Storage, Shelf life, Reliability, Disposal, Maintenance, and/or Service
All of these factors will be addressed in the Relationship Table (PR800-011 App II). However, since this is a device implanted using disposable instruments (as is TVT), using the same packaging components as TVT, there is limited risk to any of the above factors. In addition, some surgical training may be required for users not familiar with the trans-obturator approach. One kit per box packaging will be offered and labeled as a sterile, single-use device.

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Market Needs: (General statements concerning the market size, region(s), desired time of release, approximate volumes anticipated, introduction strategy)

GYNECARE TVT has rapidly gained market leadership and in the majority of countries and is now the gold standard surgical procedure for SUI with over 400,000 procedures been performed worldwide. The key drivers to the success of TVT have been the minimally invasiveness, fast patient recovery, ease of the technique, low risk of complications, consistent results and the long-term efficacy.

The most minor complication reported is bladder perforation (3-15%). Major complications such as bladder, urethra, vessel and bowel damage are very rare, however, these are always a concern when performing TVT particularly on patients who have had several surgical procedures.

In Europe there are now at least fifteen competitor type (retro pubic approach) products who all claim the same effectiveness and efficacy as GYNECARE TVT whilst having no or minimal clinical data. The competitor share is estimated to be around 20% and increasing in the coming years.

In 2001 PORGES entered the market place in Europe with a device called URATAPE (also recently launched OBTAPE) The procedure is performed via the obturator foramen with an "outside in" approach. The product is positioned as being safer than TVT as it avoids the retropubic space greatly minimizing risk to bladder, urethra, vessel and bowel, whilst also reducing the need for intra operative cystoscopy, which further reduces operative time.

Initially the approach came with great skepticism, however, since its launch has gained huge popularity in France (early adopter of TVT) and Belgium and to a lesser degrees in the other direct four countries. It is estimated that at least 3500 of these procedures have been performed in France and many of the key opinion leaders now perform the trans-obturator approach as opposed to the retropubic approach.

In January 2003 AMS also launched a trans-obturator approach device called MONARC in Europe. Activity has now been reported in France, Germany and UK. Many surgeons across Europe have been approached by AMS to participate in a randomized controlled trial. This product was launched in the US in June 2003.

Current Needs

- General market expectation for innovation beyond TVT
- Market place becoming more aware of the importance of mesh and the recognition of the key qualities of GYNECARE TVT
- A product which further reduces the risk of complications associated with the retropubic approach, particularly on patients who have had repeat surgery
- Reduce possible need for cystoscopy
- May reduce risk of post-operative voiding difficulties

Assumptions

- Mulberry will partially cannibalize TVT sales
- Mulberry will be premium price compared to TVT
- Time to market 1Q2004

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Desired Clinical & Economic Outcomes:

- Provide user with alternative system for treatment of female SUI
- Maintain market leadership and dominance in SUI treatment.